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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,945	12/05/2001	Cheryl Ann Janson	O50937	3771

20462 7590 08/19/2003

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EXAMINER

STEADMAN, DAVID J

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,945

Applicant(s)

JANSON ET AL.

Examiner

David J Steadman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Status of the Application

[1] Claims 1-27 are pending in the application.

[2] The face of the file indicates that an information disclosure statement has been received and filed as Paper No. 2. However, the examiner can find no information disclosure statement or reference(s) cited therein in the application.

[3] Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows: An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

If applicant desires priority under 35 U.S.C. 119(e) based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Lack of Unity

[4] Lack of unity is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1:

Group I, claims 1-7, drawn to the special technical feature of a composition comprising an *E. coli* FabH in crystalline form, an *E. coli* FabH crystal, a selenomethionine mutant crystal of an *E. coli* FabH.

Group II, claims 8-11, drawn to the special technical feature of an isolated properly folded FabH molecule or fragment thereof.

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Group III, claims 12 and 17, drawn to the special technical feature of a peptide, peptidomimetic or synthetic molecule that interacts competitively or non-competitively with the active site of a FabH of claim 1 or inhibits the enzymatic activity of a FabH.

Group IV, claims 13-16, drawn to the special technical feature of a method of identifying an inhibitor compound

Group V, claim 18, drawn to the special technical feature of a method for solving a crystal form.

Group VI, claims 19-27, drawn to the special technical feature of a method of drug design.

[5] The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons:

- According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The technical feature of Group II is an isolated properly folded FabH molecule or fragment thereof, which is shown by Heath et al. (*J Biol Chem* 271:10996-11000) as evidenced by Branden et al. ("Introduction to Protein Structure, Second Edition" page 375, Garland Publishing, Inc. New York, 1999) to lack novelty or inventive step because Heath et al. teach isolation of an *E. coli* FabH polypeptide (see page 10997, right column, middle) and Branden et al. teach "structures of proteins determined by x-ray crystallography are the same as those for the proteins in solution" (page 375, top), and thus the *E. coli* FabH polypeptide of Heath et al. would inherently have a conformation as set forth in claim 8 and does not make it a contribution over the prior art. Also, the technical feature of Group III is a peptide, peptidomimetic or synthetic molecule that interacts competitively or non-competitively with the active site of a crystalline *E. coli* FabH, which is shown by Heath et al. (*J Biol Chem* 271:10996-11000) to lack novelty or inventive step because Heath et al. teach acyl-ACP inhibitors of *E. coli* FabH (see page 10999, Figures 4 and 5) synthesized using an acyl-ACP synthetase (page 10997, left column, top) and does not make it a contribution over the prior art.
- According to PCT Rule 13.2, unity of invention exists only when there is a shared same or corresponding special technical feature among the claimed inventions. The FabH molecule of Group II,

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particularly the FabH of claim 8, encompasses FabH molecules that, when crystallized, do not correspond to the *E. coli* FabH in crystalline form of the composition of Group I and therefore, the FabH molecule of Group II, particularly the FabH molecule of claim 8, does not share a corresponding special technical feature with the composition of Group I, and thus the inventions do not have unity of invention.

[6] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[7] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Friday from 7:00 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for submission of official papers to Group 1600 is (703) 308-4242. Draft or informal FAX communications should be directed to (703) 746-5078. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman
Patent Examiner
Art Unit 1652

 08/17/03